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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/995,529	11/26/2001	Jeffry D. Watkins	P-IX 4976	2007

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EXAMINER	
RAWLINGS, STEPHEN L	
ART UNIT	**PAPER NUMBER**
1642	8

DATE MAILED: 10/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/995,529	WATKINS ET AL.	
	Examiner	Art Unit	
	Stephen L. Rawlings, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-83 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-83 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Claims 1-83 are pending in the application and are currently subject to the following restriction.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Claims 1-22 and 42, insofar as the claims are drawn to a grafted antibody or functional fragment thereof, which has specific binding activity for a cryptic collagen epitope, wherein said antibody comprises one or more complementarity determining regions (CDRs) having at least one amino acid substitution in one or more CDRs selected from the group consisting of SEQ ID NO: 26, SEQ ID NO: 28, SEQ ID NO: 30, SEQ ID NO: 20, SEQ ID NO: 22, and SEQ ID NO: 24, and wherein said antibody further comprises one or more CDRs selected from the group of CDRs consisting of SEQ ID NOs: 43-86 and 154-162, classified in class 530, subclass 387.3.

Note: If Applicant wishes to elect one of the inventions of claims 1-22 and 42, Applicants must do so by specifically identifying the one or more CDRs selected from the group consisting of SEQ ID NO: 26, SEQ ID NO: 28, SEQ ID NO: 30, SEQ ID NO: 20, SEQ ID NO: 22, and SEQ ID NO: 24 and the one or more CDRs selected from the group of CDRs consisting of SEQ ID NOs: 43-86 and 154-162, to which the claims are to be drawn. Any of claims 1-22 and 42, which are drawn to non-elected inventions, will be withdrawn from consideration at least to the extent that the claims are drawn to the subject matter of the non-elected inventions.

Claims 23-42, insofar as the claims are drawn to a grafted antibody or functional fragment thereof, which has specific binding activity for a cryptic collagen epitope, wherein said antibody comprises one or more complementarity determining regions (CDRs) having at least one amino acid substitution in one or more CDRs selected from the group consisting of SEQ ID NO: 38, SEQ ID NO: 40, SEQ ID NO: 42, SEQ ID NO: 32, SEQ ID NO: 34, and SEQ ID NO: 36, and wherein said antibody further comprises one or more CDRs selected from the group of CDRs consisting of SEQ ID NOs: 87-153 and 358, classified in class 530, subclass 387.3.

Note: If Applicant wishes to elect one of the inventions of claims 23-42, Applicants must do so by specifically identifying the one or more CDRs selected from the group consisting of SEQ ID NO: 38, SEQ ID NO: 40, SEQ ID NO: 42, SEQ ID NO: 32, SEQ ID NO: 34, and SEQ ID NO: 36 and the one or more CDRs selected from the group of CDRs consisting of SEQ ID NOs: 87-153 and 358, to which the claims are to be drawn. Any of claims 23-42, which are drawn to non-elected inventions, will be withdrawn from consideration at least to the extent that the claims are drawn to the subject matter of the non-elected inventions.

Claim 43, insofar as the claims are drawn to a nucleic acid molecule encoding a grafted antibody or functional fragment thereof, which has specific binding activity for a cryptic collagen epitope, wherein said antibody comprises one or more complementarity determining regions (CDRs) having at least one amino acid substitution in one or more CDRs selected from the group consisting of SEQ ID NO: 26, SEQ ID NO: 28, SEQ ID NO: 30, SEQ ID NO: 20, SEQ ID NO: 22, and SEQ ID NO: 24, and wherein said antibody further comprises one or more CDRs selected from the group of CDRs consisting of SEQ ID NOs: 43-86 and 154-162, or encoding a grafted antibody or functional fragment thereof, which has specific binding activity

for a cryptic collagen epitope, wherein said antibody comprises one or more complementarity determining regions (CDRs) having at least one amino acid substitution in one or more CDRs selected from the group consisting of SEQ ID NO: 38, SEQ ID NO: 40, SEQ ID NO: 42, SEQ ID NO: 32, SEQ ID NO: 34, and SEQ ID NO: 36, and wherein said antibody further comprises one or more CDRs selected from the group of CDRs consisting of SEQ ID NOs: 87-153 and 358, classified in class 536, subclass 23.5.

Note: If Applicant wishes to elect one of the inventions of claim 43, Applicants must do so by specifically identifying the one or more CDRs selected from the group consisting of SEQ ID NO: 26, SEQ ID NO: 28, SEQ ID NO: 30, SEQ ID NO: 20, SEQ ID NO: 22, and SEQ ID NO: 24 and the one or more CDRs selected from the group of CDRs consisting of SEQ ID NOs: 43-86 and 154-162, or the one or more CDRs selected from the group consisting of SEQ ID NO: 38, SEQ ID NO: 40, SEQ ID NO: 42, SEQ ID NO: 32, SEQ ID NO: 34, and SEQ ID NO: 36 and the one or more CDRs selected from the group of CDRs consisting of SEQ ID NOs: 87-153 and 358, to which the claim is to be drawn. Claim 43 will be withdrawn from consideration to the extent that the claim is drawn to the subject matter of non-elected inventions.

Claims 44-47, insofar as the claims are drawn a method for targeting angiogenic vasculature, wherein said method comprises administering antibody or functional fragment thereof, which has specific binding activity for a cryptic collagen epitope, wherein said antibody comprises one or more complementarity determining regions (CDRs) having at least one amino acid substitution in one or more CDRs selected from the group consisting of SEQ ID NO: 26, SEQ ID NO: 28, SEQ ID NO: 30, SEQ ID NO: 20, SEQ ID NO: 22, and SEQ ID NO: 24, and wherein said antibody further

comprises one or more CDRs selected from the group of CDRs consisting of SEQ ID NOs: 43-86 and 154-162, classified, for example, in class 424, subclass 133.1.

Note: If Applicant wishes to elect one of the inventions of claims 44-47, Applicants must do so by specifically identifying the one or more CDRs selected from the group consisting of SEQ ID NO: 26, SEQ ID NO: 28, SEQ ID NO: 30, SEQ ID NO: 20, SEQ ID NO: 22, and SEQ ID NO: 24 and the one or more CDRs selected from the group of CDRs consisting of SEQ ID NOs: 43-86 and 154-162, to which the claims are to be drawn. Claims 44-47 will be withdrawn from consideration to the extent that the claim is drawn to the subject matter of non-elected inventions.

Claims 48-50, insofar as the claims are drawn a method for inhibiting angiogenesis, wherein said method comprises administering antibody or functional fragment thereof, which has specific binding activity for a cryptic collagen epitope, wherein said antibody comprises one or more complementarity determining regions (CDRs) having at least one amino acid substitution in one or more CDRs selected from the group consisting of SEQ ID NO: 26, SEQ ID NO: 28, SEQ ID NO: 30, SEQ ID NO: 20, SEQ ID NO: 22, and SEQ ID NO: 24, and wherein said antibody further comprises one or more CDRs selected from the group of CDRs consisting of SEQ ID NOs: 43-86 and 154-162, classified, for example, in class 424, subclass 183.1.

Note: If Applicant wishes to elect one of the inventions of claims 48-50, Applicants must do so by specifically identifying the one or more CDRs selected from the group consisting of SEQ ID NO: 26, SEQ ID NO: 28, SEQ ID NO: 30, SEQ ID NO: 20, SEQ ID NO: 22, and SEQ ID NO: 24 and the one or more CDRs selected from the group of CDRs consisting of

SEQ ID NOs: 43-86 and 154-162, to which the claims are to be drawn. Claims 48-50 will be withdrawn from consideration to the extent that the claim is drawn to the subject matter of non-elected inventions.

Claims 51-54, insofar as the claims are drawn a method for targeting a tumor, wherein said method comprises administering antibody or functional fragment thereof, which has specific binding activity for a cryptic collagen epitope, wherein said antibody comprises one or more complementarity determining regions (CDRs) having at least one amino acid substitution in one or more CDRs selected from the group consisting of SEQ ID NO: 26, SEQ ID NO: 28, SEQ ID NO: 30, SEQ ID NO: 20, SEQ ID NO: 22, and SEQ ID NO: 24, and wherein said antibody further comprises one or more CDRs selected from the group of CDRs consisting of SEQ ID NOs: 43-86 and 154-162, classified, for example, in class 424, subclass 133.1.

Note: If Applicant wishes to elect one of the inventions of claims 51-54, Applicants must do so by specifically identifying the one or more CDRs selected from the group consisting of SEQ ID NO: 26, SEQ ID NO: 28, SEQ ID NO: 30, SEQ ID NO: 20, SEQ ID NO: 22, and SEQ ID NO: 24 and the one or more CDRs selected from the group of CDRs consisting of SEQ ID NOs: 43-86 and 154-162, to which the claims are to be drawn. Claims 51-54 will be withdrawn from consideration to the extent that the claim is drawn to the subject matter of non-elected inventions.

Claims 55-57, insofar as the claims are drawn a method for inhibiting tumor growth, wherein said method comprises administering antibody or functional fragment thereof, which has specific binding activity for a cryptic collagen epitope, wherein said antibody comprises one or more complementarity determining regions (CDRs) having at least one amino acid substitution in one or more CDRs selected from the group consisting

of SEQ ID NO: 26, SEQ ID NO: 28, SEQ ID NO: 30, SEQ ID NO: 20, SEQ ID NO: 22, and SEQ ID NO: 24, and wherein said antibody further comprises one or more CDRs selected from the group of CDRs consisting of SEQ ID NOs: 43-86 and 154-162, classified, for example, in class 424, subclass 181.1.

Note: If Applicant wishes to elect one of the inventions of claims 55-57, Applicants must do so by specifically identifying the one or more CDRs selected from the group consisting of SEQ ID NO: 26, SEQ ID NO: 28, SEQ ID NO: 30, SEQ ID NO: 20, SEQ ID NO: 22, and SEQ ID NO: 24 and the one or more CDRs selected from the group of CDRs consisting of SEQ ID NOs: 43-86 and 154-162, to which the claims are to be drawn. Claims 55-57 will be withdrawn from consideration to the extent that the claim is drawn to the subject matter of non-elected inventions.

Claims 58-60, insofar as the claims are drawn a method for detecting angiogenic vasculature, wherein said method comprises administering antibody or functional fragment thereof, which has specific binding activity for a cryptic collagen epitope, wherein said antibody comprises one or more complementarity determining regions (CDRs) having at least one amino acid substitution in one or more CDRs selected from the group consisting of SEQ ID NO: 26, SEQ ID NO: 28, SEQ ID NO: 30, SEQ ID NO: 20, SEQ ID NO: 22, and SEQ ID NO: 24, and wherein said antibody further comprises one or more CDRs selected from the group of CDRs consisting of SEQ ID NOs: 43-86 and 154-162, classified, for example, in class 424, subclass 1.49.

Note: If Applicant wishes to elect one of the inventions of claims 58-60, Applicants must do so by specifically identifying the one or more CDRs selected from the group consisting of SEQ ID NO: 26, SEQ ID NO: 28,

SEQ ID NO: 30, SEQ ID NO: 20, SEQ ID NO: 22, and SEQ ID NO: 24 and the one or more CDRs selected from the group of CDRs consisting of SEQ ID NOs: 43-86 and 154-162, to which the claims are to be drawn. Claims 58-60 will be withdrawn from consideration to the extent that the claim is drawn to the subject matter of non-elected inventions.

Claims 61-63, insofar as the claims are drawn a method for inhibiting metastasis, wherein said method comprises administering antibody or functional fragment thereof, which has specific binding activity for a cryptic collagen epitope, wherein said antibody comprises one or more complementarity determining regions (CDRs) having at least one amino acid substitution in one or more CDRs selected from the group consisting of SEQ ID NO: 26, SEQ ID NO: 28, SEQ ID NO: 30, SEQ ID NO: 20, SEQ ID NO: 22, and SEQ ID NO: 24, and wherein said antibody further comprises one or more CDRs selected from the group of CDRs consisting of SEQ ID NOs: 43-86 and 154-162, classified, for example, in class 424, subclass 181.1.

Note: If Applicant wishes to elect one of the inventions of claims 61-63, Applicants must do so by specifically identifying the one or more CDRs selected from the group consisting of SEQ ID NO: 26, SEQ ID NO: 28, SEQ ID NO: 30, SEQ ID NO: 20, SEQ ID NO: 22, and SEQ ID NO: 24 and the one or more CDRs selected from the group of CDRs consisting of SEQ ID NOs: 43-86 and 154-162, to which the claims are to be drawn. Claims 61-63 will be withdrawn from consideration to the extent that the claim is drawn to the subject matter of non-elected inventions.

Claims 64-67, insofar as the claims are drawn to a method for targeting angiogenic vasculature, wherein said method comprises administering an antibody or functional fragment thereof, which has specific binding activity for a cryptic collagen epitope, wherein said antibody comprises one or

more complementarity determining regions (CDRs) having at least one amino acid substitution in one or more CDRs selected from the group consisting of SEQ ID NO: 38, SEQ ID NO: 40, SEQ ID NO: 42, SEQ ID NO: 32, SEQ ID NO: 34, and SEQ ID NO: 36, and wherein said antibody further comprises one or more CDRs selected from the group of CDRs consisting of SEQ ID NOs: 87-153 and 358, classified in class 424, subclass 133.1.

Note: If Applicant wishes to elect one of the inventions of claims 64-67, Applicants must do so by specifically identifying the one or more CDRs selected from the group consisting of SEQ ID NO: 38, SEQ ID NO: 40, SEQ ID NO: 42, SEQ ID NO: 32, SEQ ID NO: 34, and SEQ ID NO: 36 and the one or more CDRs selected from the group of CDRs consisting of SEQ ID NOs: 87-153 and 358, to which the claims are to be drawn. Claims 64-67 will be withdrawn from consideration to the extent that the claim is drawn to the subject matter of non-elected inventions.

Claims 68-70, insofar as the claims are drawn to a method for inhibiting angiogenesis, wherein said method comprises administering an antibody or functional fragment thereof, which has specific binding activity for a cryptic collagen epitope, wherein said antibody comprises one or more complementarity determining regions (CDRs) having at least one amino acid substitution in one or more CDRs selected from the group consisting of SEQ ID NO: 38, SEQ ID NO: 40, SEQ ID NO: 42, SEQ ID NO: 32, SEQ ID NO: 34, and SEQ ID NO: 36, and wherein said antibody further comprises one or more CDRs selected from the group of CDRs consisting of SEQ ID NOs: 87-153 and 358, classified in class 424, subclass 183.1.

Note: If Applicant wishes to elect one of the inventions of claims 68-70, Applicants must do so by specifically identifying the one or more CDRs

selected from the group consisting of SEQ ID NO: 38, SEQ ID NO: 40, SEQ ID NO: 42, SEQ ID NO: 32, SEQ ID NO: 34, and SEQ ID NO: 36 and the one or more CDRs selected from the group of CDRs consisting of SEQ ID NOs: 87-153 and 358, to which the claims are to be drawn. Claims 68-70 will be withdrawn from consideration to the extent that the claim is drawn to the subject matter of non-elected inventions.

Claims 71-74, insofar as the claims are drawn to a method for targeting a tumor, wherein said method comprises administering an antibody or functional fragment thereof, which has specific binding activity for a cryptic collagen epitope, wherein said antibody comprises one or more complementarity determining regions (CDRs) having at least one amino acid substitution in one or more CDRs selected from the group consisting of SEQ ID NO: 38, SEQ ID NO: 40, SEQ ID NO: 42, SEQ ID NO: 32, SEQ ID NO: 34, and SEQ ID NO: 36, and wherein said antibody further comprises one or more CDRs selected from the group of CDRs consisting of SEQ ID NOs: 87-153 and 358, classified in class 424, subclass 133.1.

Note: If Applicant wishes to elect one of the inventions of claims 71-74, Applicants must do so by specifically identifying the one or more CDRs selected from the group consisting of SEQ ID NO: 38, SEQ ID NO: 40, SEQ ID NO: 42, SEQ ID NO: 32, SEQ ID NO: 34, and SEQ ID NO: 36 and the one or more CDRs selected from the group of CDRs consisting of SEQ ID NOs: 87-153 and 358, to which the claims are to be drawn. Claims 71-74 will be withdrawn from consideration to the extent that the claim is drawn to the subject matter of non-elected inventions.

Claims 75-77 and 81-83, insofar as the claims are drawn to a method for inhibiting tumor growth, wherein said method comprises administering an antibody or functional fragment thereof, which has specific binding activity

for a cryptic collagen epitope, wherein said antibody comprises one or more complementarity determining regions (CDRs) having at least one amino acid substitution in one or more CDRs selected from the group consisting of SEQ ID NO: 38, SEQ ID NO: 40, SEQ ID NO: 42, SEQ ID NO: 32, SEQ ID NO: 34, and SEQ ID NO: 36, and wherein said antibody further comprises one or more CDRs selected from the group of CDRs consisting of SEQ ID NOs: 87-153 and 358, classified in class 424, subclass 181.1.

Note: If Applicant wishes to elect one of the inventions of claims 75-77 and 81-83, Applicants must do so by specifically identifying the one or more CDRs selected from the group consisting of SEQ ID NO: 38, SEQ ID NO: 40, SEQ ID NO: 42, SEQ ID NO: 32, SEQ ID NO: 34, and SEQ ID NO: 36 and the one or more CDRs selected from the group of CDRs consisting of SEQ ID NOs: 87-153 and 358, to which the claims are to be drawn. Claims 75-77 and 81-83 will be withdrawn from consideration to the extent that the claim is drawn to the subject matter of non-elected inventions.

Claims 78-80, insofar as the claims are drawn to a method for detecting angiogenic vasculature, wherein said method comprises administering an antibody or functional fragment thereof, which has specific binding activity for a cryptic collagen epitope, wherein said antibody comprises one or more complementarity determining regions (CDRs) having at least one amino acid substitution in one or more CDRs selected from the group consisting of SEQ ID NO: 38, SEQ ID NO: 40, SEQ ID NO: 42, SEQ ID NO: 32, SEQ ID NO: 34, and SEQ ID NO: 36, and wherein said antibody further comprises one or more CDRs selected from the group of CDRs consisting of SEQ ID NOs: 87-153 and 358, classified in class 424, subclass 1.49.

Note: If Applicant wishes to elect one of the inventions of claims 78-80, Applicants must do so by specifically identifying the one or more CDRs selected from the group consisting of SEQ ID NO: 38, SEQ ID NO: 40, SEQ ID NO: 42, SEQ ID NO: 32, SEQ ID NO: 34, and SEQ ID NO: 36 and the one or more CDRs selected from the group of CDRs consisting of SEQ ID NOs: 87-153 and 358, to which the claims are to be drawn. Claims 78-80 will be withdrawn from consideration to the extent that the claim is drawn to the subject matter of non-elected inventions.

3. The inventions are distinct, each from the other because of the following reasons:

The inventions of the groups of claims 1-22 and 42 and claims 23-42, and the inventions of claim 43 are disclosed as biologically and chemically distinct, unrelated in structure and/or function, and/or made by and/or used in different methods, and therefore the claimed products are distinct.

The inventions of the groups of claims of 44-47, 48-50, 51-54, 55-57, 58-60, 61-63, 64-67, 68-70, 71-74, 75-77, 78-80, and 81-83 are disclosed as materially different methods that differ at least in objectives, method steps, reagents and/or doses and/or schedules used, response variables, assays for end products and/or results, and criteria for success, and therefore the claimed methods are distinct.

Inventions of the groups of claims 1-22 and 42 and the inventions of the groups of claims of 44-47, 48-50, 51-54, 55-57, 58-60, 61-63, 64-67, 68-70, 71-74, 75-77, 78-80, and 81-83 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed, namely antibody or functional fragment thereof can be used in a materially different process of using that product, such as the process of purifying the protein to which the antibody binds by affinity chromatography.

The inventions of claim 43 and the inventions of the groups of claims of 44-47, 48-50, 51-54, 55-57, 58-60, 61-63, 64-67, 68-70, 71-74, 75-77, 78-80, and 81-83 are not at all related because the products of claim 43 are not specifically used in any of the steps of the claimed methods of claims of 44-47, 48-50, 51-54, 55-57, 58-60, 61-63, 64-67, 68-70, 71-74, 75-77, 78-80, and 81-83.

4. Because these inventions are distinct for the reasons given above and also because the search required for any one group is not required for any other group and/or the inventions have acquired a separate status in the art as shown by their different classification or their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. Claims 1, 2, 21-24, 40, 41, 44, 45, 48, 49, 51, 52, 55, 56, 58, 59, 61, 62, 64, 65, 68, 69, 71, 72, 75, 76, 78, 79, 81, and 82 are linking claims. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s). Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim depending from or otherwise including all the limitations of the allowable linking claims will be entitled to examination in the instant application. Applicants are advised that if any such claims depending from or including all the limitations of the allowable linking claims are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

7. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (703) 305-3008. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C. Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

/ Rawlings / STEPHEN RAWLINGS

Stephen L. Rawlings, Ph.D.
Examiner
Art Unit 1642

slr
October 20, 2003